

What is claimed is:

1. A medical device, comprising:

a tubular sheath having a plurality of spaced apart wire stabilization guides, said

wire stabilization guides comprising elongated tubular members having at least a portion

thereof extending from an end of said sheath;

a retention device formed on said portion of at least one wire stabilization guide

extending from said end of said sheath, said retention device comprising a portion of said

wire stabilization guide adapted to selectively expand outwardly from said wire

stabilization guide in at least one direction.

2. A device as claimed in claim 1, further comprising a guide rod sized to fit within

said tubular sheath and having at least one slot formed along its length, said at least one

slot releaseably holding one respective said wire stabilization guide.

3. A medical device as claimed in claim 1, further comprising wire moveably

disposed within said wire stabilization guides, said wire being fixed to said wire

stabilization guide at a point along said wire stabilization guide, wherein movement of

said wire in a proximal direction causes a compression of said wire stabilization guide

thereby forming said retention device.

4. A medical device as claimed in claim 3, said retention device comprises a slit on

one or more sides of said tubular stabilization guides and wherein said wire being drawn

proximally thereby compresses said retention device causing a portion of said

stabilization guide about said slitto expand outwardly in at least one direction.

5. A medical device as claimed in claim 3, said retention device comprising one or

more notch sections of said tubular stabilization guides and wherein said wire being

drawn proximally thereby compresses said retention device and causes a portion of said stabilization guide about said notch to expand outwardly in at least one direction.

6. A medical device as claimed in claim 5, wherein said notch sections are generally symmetrical on either side of said tubular stabilization guide, wherein compression of said tubular stabilization guide causes folds at said notch sections.

7. A medical device as claimed in claim 3, said retention device comprises one or more filament attached to said tubular stabilization guides and wherein said wire being drawn proximally thereby compressing said retention device and causing said one or more filaments to expand outwardly in at least one direction.

8. A medical device, comprising:

a tubular sheath having two wire stabilization guides, said wire stabilization guides comprising an elongated tubular member having at least a portion thereof extending from an end of said sheath;

a retention device formed on said portion of said wire stabilization guide extending from said end of said sheath, said retention device comprising a portion of said wire stabilization guide adapted to selectively expand outwardly in at least one direction and further comprising a wire having two ends threaded into said wire stabilization guides and moveably disposed within said wire stabilization guides and thus forming a loop extending from said end of said sheath, said wire being fixed to each said wire stabilization guide.

9. A medical device as claimed in claim 8, said retention device comprises a slit on at least one side of said tubular stabilization guides and wherein said wire being drawn proximally thereby compressing said stabilization guides at said point where said wire is

about said slit to expand outwardly in at least one direction.

10. A medical device as claimed in claim 8, said retention device comprising one or more notch sections of said tubular stabilization guides and wherein said wire being drawn proximally thereby compresses said retention device and causes a portion of said stabilization guide about said notch to expand outwardly in at least one direction.

more notch sections of said tubular stabilization guides and wherein said wire being

drawn proximally thereby compresses said retention device and causes a portion of said stabilization guide about said notch to expand outwardly in at least one direction.

stabilization guide about said notch to expand outwardly in at least one direction.

11. A medical device as claimed in claim 10, wherein said notch sections are generally symmetrical on either side of said tubular stabilization guide, wherein compression of said tubular stabilization guide causes folds at said notch section.

generally symmetrical on either side of said tubular stabilization guide, wherein

compression of said tubular stabilization guide causes folds at said notch sections.

12. A medical device as claimed in claim 8, said retention device comprises one or more filament attached to said tubular stabilization guides and wherein said wire being drawn proximally thereby compressing said retention device and causing said one or more filaments to expand outwardly in at least one direction.

more filament attached to said tubular stabilization guides and wherein said wire being

drawn proximally thereby compressing said retention device and causing said one or

more filaments to expand outwardly in at least one direction.

13. A medical device as claimed in claim 1, said retention device securing said sheath to an arterial wall to prevent transverse movement of said sheath with respect to a wound site in said arterial wall.

to an arterial wall to prevent transverse movement of said sheath with respect to a wound

site in said arterial wall.

14. A medical device as claimed in claim 8, said selectively deployable extension member securing said sheath to an arterial wall to prevent transverse movement of said sheath with respect to a wound site in said arterial wall.

member securing said sheath to an arterial wall to prevent transverse movement of said

sheath with respect to a wound site in said arterial wall.

15. A medical device as claimed in claim 1, wherein said wire stabilization guides being disposed opposite one another on said sheath approximately 180 degrees apart.

being disposed opposite one another on said sheath approximately 180 degrees apart.

16. A medical device as claimed in claim 7, wherein said wire stabilization guides being disposed opposite one another approximately 180 degrees apart.

being disposed opposite one another approximately 180 degrees apart.

17. A medical device as claimed in claim 1, wherein said wire stabilization guides are placed into a wound site in an artery or vein such that said wire stabilization guides are transverse to a long axis of said artery or vein.

18. A medical device as claimed in claim 7, wherein said wire stabilization guides are placed into a wound site in an artery or vein such that said wire stabilization guides are transverse to a long axis of said artery or vein.

19. A medical device as claimed in claim 17, wherein said wire stabilization guides urge said wound site into an elongated configuration.

20. A medical device as claimed in claim 18, wherein said wire stabilization guides urge said wound site into an elongated configuration.

21. A medical device as claimed in claim 14, wherein said loop is internal within said wound site when said wire stabilization guides are placed within said wound site.

22. A method for stabilizing a wound in an artery or vein, said method comprising the steps of:

approximating an elongated sheath to a wound site;

placing a loop activation wire into said wound site;

placing said loop activation wire approximate to tissue surrounding said wound site; and

deploying a retention device extending from said loop, said retention device securing said sheath to said wound site.

23. A method as claimed in claim 22, further comprising the step of allowing opposing sides of said tissue surrounding said wound site to approximate one another.

1 24. A method as claimed in claim 22, further comprising the steps of retracting said
2 retention device and removing said loop activation wire from said wound site.

3 25. A method for stabilizing a wound site, said method comprising:

4 approximating an elongated sheath to a wound site;

5 inserting two wire stabilization guides into said wound site;

6 and deploying a retention device, said retention device securing said sheath to said
7 wound site.

8 26. A method as claimed in claim 25, further comprising the step of positioning said
9 wire stabilization guides wherein into said wound site such that said wire stabilization
10 guides are transverse to a long axis of said artery or vein.

11 27. A method as claimed in claim 25, further comprising the step of allowing
12 opposing sides of said tissue surrounding said wound site to approximate one another.

13 28. A medical device as claimed in claim 1, said sheath further comprises an
14 expandable distal tip section.

15 29. A medical device as claimed in claim 8, said sheath further comprises an
16 expandable distal tip section.

17 30. A medical device as claimed in claim 28, wherein said sheath is approximated to
18 tissue surrounding a wound site to hold said sheath approximately centered on said
19 wound site when said distal tip of said sheath expands.

20 31. An introducer, comprising:

21 a tubular sheath having two hollow wire stabilization guides, said wire

22 stabilization guides comprising an elongated tubular member having at least a portion

23 thereof extending from an end of said sheath;

a guide rod sized to fit within said tubular sheath and having slots formed along its length, said slots releaseably holding said wire stabilization guides;

a retention device formed on said portion of said wire stabilization guide extending from said end of said sheath, said retention device comprising a portion of said wire stabilization guide adapted to selectively expand outwardly in at least one direction; and a wire moveably disposed within each said wire stabilization guide, said wire being fixed to said wire stabilization guide at a point along said wire stabilization guide that is distal to said retention device.

32. An introducer as claimed in claim 31, wherein said wire being moved relative to said stabilization guide to deploy said retention device.

33. An introducer as claimed in claim 31, wherein said wire being moved relative to said stabilization guide to retract said retention device.

34. An introducer as claimed in claim 31, wherein said wire stabilization guides are placed in a wound site formed in an artery or vein and disposed along a transverse axis relative to a long axis of said artery or vein.

35. An introducer and claimed in claim 31, wherein said sheath further comprises an expandable distal tip section and wherein when said sheath is approximated to a wound site and a radial force is applied to the distal end of said sheath in a direction generally perpendicular to the central axis of said sheath, said expandable section expands, thereby increasing the diameter of said sheath.

36. An introducer as claimed in claim 35, wherein said sheath is approximated to tissue surrounding said wound site to hold said sheath approximately centered on said wound site when the diameter of said expandable section increases.

37. An introducer as claimed in claim 31, wherein said guide rod further comprises a first and a second blood marking lumen, each said lumen having a flashback port at a first end and a blood marking port at a second end, the blood marking port of the first said lumen being fixedly disposed to said device at a shorter distance from a wound site than the blood marking port of said second lumen; wherein the fact that the blood marking port of the first lumen is adjacent to the outer wall of said artery or vein is indicated when pressurized blood flow is present at the first said lumen and absent at said second lumen.

38. An introducer, comprising:

a tubular sheath having two wire stabilization guides, said wire stabilization guides comprising elongated tubular members having at least a portion thereof extending from an end of said sheath;

a guide rod sized to fit within said tubular sheath and having two slots formed along its length, at least one slot releaseably holding one respective said wire stabilization guide;

a retention device formed on said portion of said wire stabilization guide
extending from said end of said sheath, said retention device comprising a portion of said
wire stabilization guide adapted to selectively expand outwardly in at least one direction;
and

a wire having two ends, each said end threaded into a respective said wire stabilization guide and thus forming a loop of wire from the wire protruding from said wire stabilization guides extending from said end of said sheath.

39. A medical device, comprising:

1 a tubular sheath having two wire stabilization guides, said wire stabilization
2 guides comprising elongated tubular members having at least a portion thereof extending
3 from an end of said sheath;

4 a selectively deployable retention device extending from portion of said wire
5 stabilization guide extending from said end of said sheath, said selectively deployable
6 retention device securing said sheath to an arterial wall.

7 40. A medical device, comprising a tubular sheath having two spaced apart wire
8 stabilization guides, said wire stabilization guides comprising elongated tubular members
9 having at least a portion thereof extending from an end of said sheath, said sheath further
10 comprising an expandable distal tip section.

11 41. A medical device as claimed in claim 40, further comprising a guide rod sized to
12 fit within said tubular sheath, and having slots formed along its length, said slots
13 releaseably holding said wire stabilization guides.

14 42. A medical device as claimed in claim 40, wherein said wire stabilization guides
15 are placed within a wound site formed in an artery or vein, and said slit or weakened tear
16 seam permits expansion of said distal end of said sheath, thereby causing said wire
17 stabilization guides to stretch said wound site along the long axis of said wound site.

18 43. A medical device as claimed in claim 42, wherein stretching said wound site
19 causes tissue along opposing sides of the short axis of said wound site to approximate
20 each other.

21 44. An introducer, comprising:
22 a tubular sheath and a transition sheath slideably disposed over at least a portion of
23 said sheath.

1 45. An introducer as claimed in claim 44, said sheath having at least two stabilization
2 guides slideably attached to said sheath, said stabilization guides having at least a portion
3 thereof extending from a distal end of said sheath.

4 46. An introducer as claimed in claim 45, said sheath transition sheath disposed over
5 said distal end of said sheath.

6 47. An introducer as claimed in claim 45, further comprising an elongated dilator
7 slideably disposed within said sheath and having a flexible tip portion extending from
8 said sheath.

9 48. An introducer as claimed in 47, said dilator comprising a first slot releasably
10 holding one of said stabilization guides, and a second slot releasably holding another said
11 stabilization guide.

12 49. An introducer as claimed in claim 47, said dilator comprising a central lumen
13 dimensioned to accept a wire guide therethrough.

14 50. An introducer as claimed in claim 45, said stabilization guides comprising flexible
15 or rigid elongated tubular or solid members.

16 51. An introducer as claimed in claim 50, further comprising a retention device
17 formed on said portion of said wire stabilization guide extending from said end of said
18 sheath, said retention device comprising a portion of said wire stabilization guide adapted
19 to selectively expand outwardly from said wire stabilization guide in at least one
20 direction.

21 52. An introducer as claimed in claim 50, further comprising wire moveably disposed
22 within said wire stabilization guides, said wire being fixed to said wire stabilization guide
23 at a point along said wire stabilization guide, wherein movement of said wire in a

proximal direction causes a compression of said wire stabilization guide thereby forming said retention device.

53. An introducer as claimed in claim 52, said retention device comprises a slit on at least two sides of said tubular stabilization guides and wherein said wire being drawn proximally thereby compressing said retention device and causing a portion of said stabilization guide about said slit to expand outwardly in at least one direction.

54. An introducer as claimed in claim 52, said retention device comprises one or more notch sections of said tubular stabilization guides and wherein said wire being drawn proximally thereby compressing said retention device and causing a portion of said stabilization guide about said notch to expand outwardly in at least one direction.

55. An introducer as claimed in claim 54, wherein said notch sections are generally symmetrical on either side of said tubular stabilization guide, wherein compression of said tubular stabilization guide causes folds at said notch sections.

56. An introducer as claimed in claim 52, said retention device comprises one or more filament attached to said tubular stabilization guides and wherein said wire being drawn proximally thereby compressing said retention device and causing said one or more filaments to expand outwardly in at least one direction.

57. An introducer as claimed in claim 44, said sheath comprising slots formed at the portion covered by said transition sheath.

58. An introducer, comprising:

a tubular sheath;

a transition sheath slideably disposed over at least a portion of said sheath; and

an elongated dilator slideably disposed within said sheath and having a flexible tip portion extending from said sheath.

59. An introducer as claimed in claim 58, further comprising an actuator portion connected to said sheath and said transition sheath comprising a transition sheath retractor and a dilator handle.

60. An introducer as claimed in claim 59, wherein said dilator handle and retractor are each slidably disposed on a dilator slide member, and wherein said retractor is slidably disposed on the receiver/sheath assembly.

61. An introducer as claimed in claim 58, wherein said transition sheath is disposed over the juncture between the distal end of the sheath and the flexible tip portion of the guide rod extending from the distal end of said sheath.

62. An introducer as claimed in claim 59, wherein said transition sheath retractor causing said transition sheath to slide over said sheath.

63. An introducer as claimed in claim 59, said sheath comprising at least two tubular stabilization guides slideably attached to said sheath and having a portion thereof extending from a distal end of said sheath, a retention device formed on said portion of said stabilization guide extending from said end of said sheath, said retention device comprising a portion of said stabilization guide adapted to selectively expand outwardly in at least one direction; and a wire moveably disposed within each said stabilization guide, said wire being fixed to said wire stabilization guide at a point along said wire stabilization guide; and

said actuator portion comprising a retention device actuator attached to said wire and causing said wire to move within said stabilization guide to deploy or retract said

retention device and to cause said stabilization guides to slide proximally with respect to the distal end of said sheath thereby moving said retention device toward the distal end of the sheath.

64. An introducer, comprising:

a sheath having an inside diameter and a distal end,

a dilator sized to fit within the inside diameter of the sheath,

a plurality of flexible wire guides having first ends and second ends, the first ends coupled to the distal end of the sheath, wherein the sheath being approximated to a wound site and the wire guides placed into a tissue wound site, said wire guides causing outward pressure along the long axis of said wound site.

65. The introducer of claim 64, wherein the guide wires are coupled to the sheath in geometrical opposed positions.

66. The introducer of claim 64, wherein the wire guides urge the wound opening into an elongated configuration.

67. The introducer of claim 65, wherein said wound site is formed in an artery or vein and at least two of said guide wires placed at opposing ends of said wound..

68. The introducer of claim 64, further comprising a blood marker to signal when said dilator is inserted into the wound opening to a predetermined depth.

69. An introducer, comprising:

a tubular sheath, and

at least two flexible wire guides extending from said sheath in geometrically opposed positions, said wire guide placed into a tissue wound site, said wire guides

causing outward pressure along the long axis of said wound site and holding said sheath approximately centered on said wound site.

70. An introducer as claimed in claim 69, wherein said wound site is formed in an artery or vein and said two of wire guides placed in said wound along a transverse axis relative to a long axis of said artery or vein.

71. An introducer of claim 64, further comprising a dilator inserted into said tubular sheath, at least a portion of said dilator being also inserted into said wound.

72. An introducer as claimed in claim 71, said dilator further comprising a fluid passageway to permit fluid to flow therethrough to indicate when said dilator is inserted into the wound opening to a predetermined depth.

73. An introducer as claimed in claim 71, wherein a portion of said wire guide being removably attached to said dilator.

74. An introducer as claimed in claim 64, wherein said sheath having an outside diameter approximately equal to the diameter of said wound.

75. A medical device, comprising:
a sheath having an inside diameter and a distal end,
and a plurality of flexible wire guides coupled to said sheath and extending from the distal end of said sheath, wherein the sheath being approximated to a wound site and the wire guides placed into a tissue wound site, said wire guides causing outward pressure along the long axis of said wound site.